



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0002]

Withdrawal of Approval of New Animal Drug Applications; Arsanilic Acid

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new animal drug application (NADA) for an arsanilic acid Type A medicated article at the sponsor's request because the product is no longer manufactured or marketed.

DATES: Withdrawal of approval is effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: John Bartkowiak, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9079, john.bartkowiak@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Fleming Laboratories, Inc., P.O. Box 34384, Charlotte, NC 28234 has requested that FDA withdraw approval of NADA 008-019 for PRO-GEN (arsanilic acid) Type A medicated article because the product, used to manufacture Type B and Type C medicated feeds, is no longer manufactured or marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with § 514.116 Notice of withdrawal of approval of application (21 CFR 514.116), notice is given that approval of NADA 008-019, and all supplements and amendments thereto, is hereby withdrawn.

Elsewhere in this issue of the Federal Register, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of this application.

Dated: November 20, 2013.

Bernadette Dunahm,

Director,

Center for Veterinary Medicine.

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